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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,188	07/11/2001	Edward M. De Robertis	510015-258	1059

7590 05/27/2004

Attention : Charles Berman
OPPENHEIMER WOLFF & DONNELLY
38th Floor
2029 Century Park East
Los Angeles, CA 90067-3024

EXAMINER

ROMEO, DAVID S

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 05/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/903,188	DE ROBERTIS ET AL.	
	Examiner	Art Unit	
	David S Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 22 August 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 6-8, 11 and 12 is/are pending in the application.
4a) Of the above claim(s) 11 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 6-8 and 12 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) 6-8, 11 and 12 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 0402.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: ____.

DETAILED ACTION

The preliminary amendments filed 11/17/2003 and 07/11/2001 have been entered.

Claims 6-8, 11, 12 are pending.

5

Applicant's election of group I, claims 6-8, 12, in Paper No./the paper filed 08/22/2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

10

Applicant's election of the polypeptide encoded by SEQ ID NO: 10 or comprising the amino acid sequence of SEQ ID NO: 9 species in Paper No./the paper filed 12/08/2003 is acknowledged.

15

Claim 11 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No./the paper filed 08/22/2003.

20

Claims 6-8, 12 are being examined. Claim 12 is being examined only to the extent that it reads upon the polypeptide encoded by SEQ ID NO: 10 or comprising the amino acid sequence of SEQ ID NO: 9 species.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must

5 contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

10 It is acknowledged that the present application contains a specific reference to the 08/874,474 prior application in the first sentence of the specification. However, the specific reference to the 08/874,474 prior nonprovisional application does not include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications. The status of nonprovisional parent application(s) (whether patented or

15 abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If a benefit claim to a provisional application is submitted without an indication

20 that an intermediate application directly claims the benefit of the provisional application and the instant nonprovisional application is not filed within the 12 month period or the relationship between each nonprovisional application is not indicated, the Office will not recognize such benefit claim and will not include the benefit claim on the filing receipt.

Therefore, a petition under 37 CFR 1.78(a) and the surcharge set forth in 37 CFR 1.17(t)

will be required if the intermediate application and the relationship of each

nonprovisional application are not indicated within the period set forth in 37 CFR

1.78(a). Even if the Office has recognized a benefit claim by entering it into the Office's

5 database and including it on applicant's filing receipt, the benefit claim is not a proper

benefit claim under 35 U.S.C. 119(e) or 35 U.S.C. 120 and 37 CFR 1.78 unless the

reference is included in an ADS or in the first sentence of the specification and all other

requirements are met. Accordingly, the benefit of the filing dates of the 08/874,474

nonprovisional application and the 60/020,150 provisional application is denied.

10 It is acknowledged that Applicants submitted a petition on 11/17/2003 to accept

an unintentionally delayed claim for priority. However, that petition has been dismissed.

See the paper mailed 05/21/2004.

Claim Rejections - 35 USC § 102

15 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20 Claims 6-8, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by De
Robertis (N).

Art Unit: 1647

This rejection is being made because the Office does not recognize Applicants benefit claims to the 08/874,474 nonprovisional application and the 60/020,150 provisional application, as discussed above.

De Robertis discloses a substantially pure protein characterized by a 5 physiologically active form and comprising an amino acid sequence encoded by the DNA of SEQ ID NO: 10 (page 25, claim 6). De Robertis's SEQ ID NO: 10 is identical to the present application's SEQ ID NO: 10, as indicated below (Qy = the present application's SEQ ID NO: 10) (Db = De Robertis's SEQ ID NO: 10):

10 AAV14017
 ID AAV14017 standard; cDNA; 1893 BP.
 XX
 AC AAV14017;
 XX
 DT 09-JUL-1998 (first entry)
 XX
 DE Human "frizzled" frzb-1 cDNA.
 XX
 KW Growth factor; frizzled; frzb-1; Wnts antagonist; human;
 KW tumour suppressor; cancer; ds.
 XX
 OS Homo sapiens.
 XX
 FH Key Location/Qualifiers
 PT CDS 61..1038
 FT /*tag= a
 FT /product= frzb-1_protein
 XX
 PN WO9748275-A1.
 XX
 PD 24-DEC-1997.
 XX
 PF 19-JUN-1997; 97WO-US10942.
 XX
 PR 18-JUN-1997; 97US-0878474.
 PR 20-JUN-1996; 96US-0020150.
 XX
 PA (REGC) UNIV CALIFORNIA.
 XX
 PI Bouwmeester T, De Robertis EM;
 XX
 DR WPI; 1998-062760/06.
 DR P-PSDB; AAW41254.
 XX
 PT New isolated growth factors - with neurotrophic, growth or
 PT differentiation factor activity, tumour growth suppressor activity
 PT or mesoderm differentiation activity
 XX
 PS Claim 6; Fig 10; 48pp; English.
 XX
 CC The present sequence encodes the human growth factor protein
 CC "frizzled" frzb-1. frzb-1 is an antagonist of Wnts in vivo, and
 CC thus is believed to find utility as a tumour suppressor gene,
 CC since overexpressed Wnt proteins cause cancer. Frzb-1 may also be a
 CC useful vehicle for solubilisation and therapeutic delivery of
 CC complexed Wnt proteins.
 XX
 SQ Sequence 1893 BP; 516 A; 438 C; 432 G; 507 T; 0 other;
 60 Query Match 100.0%; Score 1893; DB 19; Length 1893;
 Best Local Similarity 100.0%; Pred. No. 0;
 Matches 1893; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
 Qy 1 GGCAGAGCGGGCTTTGGCGTCCACTGCGGGCTGACCCCTGCCCATCTGCCGGATC 60
 |||||
 Db 1 GGCAGAGCGGGCTTTGGCGTCCACTGCGGGCTGACCCCTGCCCATCTGCCGGATC 60
 Qy 61 ATGGTCTGCGGAGAGGGATGCTGCTGCTGCGGGCTGCTGCCCTGCT 120
 |||||

Art Unit: 1647

Db 61 ATGGTCTGCCGACGGGGGGGGGGATGCTGCTGCTGCCGGGGCTGCTTGCCTGGCT 120
 QY 121 GCTCTCTGCCTGCTCCGGGTCGCCGGGGCTCGGGCTGCAGCCCTGTGAGGCCGTCGCATC 180
 5 Db 121 GCTCTCTGCCTGCTCCGGGTCGCCGGGGCTCGGGCTGCAGCCCTGTGAGGCCGTCGCATC 180
 QY 181 CCCCTGTGCAAGTCCCCTGGAACATGACTAAGATGCCAACCCACCTGACACAGC 240
 |||||||
 10 Db 181 CCCCTGTGCAAGTCCCCTGGAACATGACTAAGATGCCAACCCACCTGACACAGC 240
 QY 241 ACTCAGGCCAACGCCATCCCTGCCATCGAGCAGTTCGAAGGGCTGCTGGGACCCACTGC 300
 Db 241 ACTCAGGCCAACGCCATCCCTGCCATCGAGCAGTTCGAAGGGCTGCTGGGACCCACTGC 300
 15 QY 301 AGCCCGATCTGCTCTCTCTGTGCCATGTACGCGCCATCTGCCACATTGACTTC 360
 |||||||
 Db 301 AGCCCGATCTGCTCTCTCTGTGCCATGTACGCGCCATCTGCCACATTGACTTC 360
 20 QY 361 CAGCACGAGGCCATCAAGCCCTGTAAGTCTGTGCGAGCGGGCCCGGAGGGCTGTGAG 420
 |||||||
 Db 361 CAGCACGAGGCCATCAAGCCCTGTAAGTCTGTGCGAGCGGGCCCGGAGGGCTGTGAG 420
 QY 421 CCCATACTCATCAAGTACGCCACTCGTGGCGAGAACCTGGCTGCAGGAGCTGCCA 480
 25 Db 421 CCCATACTCATCAAGTACGCCACTCGTGGCGAGAACCTGGCTGCAGGAGCTGCCA 480
 QY 481 GTGTACGACAGGGCGTGTGCATCTCTCCGAGGCCATCGTTACTGCGGACGGAGCTGAT 540
 |||||||
 30 Db 481 GTGTACGACAGGGCGTGTGCATCTCTCCGAGGCCATCGTTACTGCGGACGGAGCTGAT 540
 QY 541 TTCTCTATGAACTTAGTAACGGAAACTGTAGAGGGGCAAGCAGTGAACGCTGTAAATGT 600
 |||||||
 Db 541 TTCTCTATGAACTTAGTAACGGAAACTGTAGAGGGGCAAGCAGTGAACGCTGTAAATGT 600
 35 QY 601 AAGCTTATTAGAGCTACACAGAAGACCTATTCCGGAACATTACAACTATGCTATTGG 660
 |||||||
 Db 601 AAGCTTATTAGAGCTACACAGAAGACCTATTCCGGAACATTACAACTATGCTATTGG 660
 40 QY 661 GCTAAAGTTAAAGAGATAAAGACTAAGTGCCTGATGTGACTGCACTAGTGGAGGTGAAG 720
 |||||||
 Db 661 GCTAAAGTTAAAGAGATAAAGACTAAGTGCCTGATGTGACTGCACTAGTGGAGGTGAAG 720
 QY 721 GAGATTCTAAAGTCCCTCTGTGTAACATTCACCGGACACTGTCACCTCTATACCGC 780
 |||||||
 45 Db 721 GAGATTCTAAAGTCCCTCTGTGTAACATTCACCGGACACTGTCACCTCTATACCGC 780
 QY 781 TCTGGCTGCCCTGCCCTCCACTTAATGTTAATGAGGAATATATCATCATGGCTATGAA 840
 |||||||
 50 Db 781 TCTGGCTGCCCTGCCCTCCACTTAATGTTAATGAGGAATATATCATCATGGCTATGAA 840
 QY 841 GATGAGGAACGTTCCAGATTACTCTTGGTGGAAAGGCTCTATAGCTGAGAAGTGGAGGAT 900
 |||||||
 Db 841 GATGAGGAACGTTCCAGATTACTCTTGGTGGAAAGGCTCTATAGCTGAGAAGTGGAGGAT 900
 55 QY 901 CGACTCGGTAAAAAGTTAAGGGCTGGGATATGAAGCTCGTCATCTGGACTCAGTAAA 960
 |||||||
 Db 901 CGACTCGGTAAAAAGTTAAGGGCTGGGATATGAAGCTCGTCATCTGGACTCAGTAAA 960
 60 QY 961 AGTGATTCTAGCAATAGTGAATTCCACTCAGAGTCAGAAGTCTGGCAGGAACCTGAAACCC 1020
 |||||||
 Db 961 AGTGATTCTAGCAATAGTGAATTCCACTCAGAGTCAGAAGTCTGGCAGGAACCTGAAACCC 1020
 QY 1021 CGGCAAGCACGCAACTAAATCCGAAATACAAAAGTAACACACTGGACTTCTATTAAAG 1080
 |||||||
 Db 1021 CGGCAAGCACGCAACTAAATCCGAAATACAAAAGTAACACACTGGACTTCTATTAAAG 1080
 QY 1081 ACTTACTTGCATTGCTGACTAGCAAAGGAAAATTGCACTATTGCACATCATATTCTATT 1140
 |||||||
 65 Db 1081 ACTTACTTGCATTGCTGACTAGCAAAGGAAAATTGCACTATTGCACATCATATTCTATT 1140
 QY 1141 GTTTACTATAAAATCATGTGATAACTGATTATTACTCTGTGTTCTCTTGTGTTCTGC 1200
 |||||||
 Db 1141 GTTTACTATAAAATCATGTGATAACTGATTATTACTCTGTGTTCTCTTGTGTTCTGC 1200
 70 QY 1201 TTCTCTCTCTCTCACCCCTTGTAAATGGTTGGGGCAGACTCTTAAGTATATTGTGA 1260
 |||||||
 Db 1201 TTCTCTCTCTCACCCCTTGTAAATGGTTGGGGCAGACTCTTAAGTATATTGTGA 1260
 QY 1261 GTTTCTATTCACAAATCATGAGAAAAGTGTCTTTGCAATAATAATAAAATTAACCA 1320
 |||||||
 Db 1261 GTTTCTATTCACAAATCATGAGAAAAGTGTCTTTGCAATAATAATAAAATTAACCA 1320
 QY 1321 TGCTGTTACAGAGGCCCTTGTGAGCTCCAGATGTTAATTACTTCTGCACCCCAA 1380
 |||||||
 85 Db 1321 TGCTGTTACAGAGGCCCTTGTGAGCTCCAGATGTTAATTACTTCTGCACCCCAA 1380
 QY 1381 TTGGGAATGCAATATTGGATGAAAAGAGAGGGTTCTGGTATTCAAGAAGCTAGATATG 1440
 |||||||
 Db 1381 TTGGGAATGCAATATTGGATGAAAAGAGAGGGTTCTGGTATTCAAGAAGCTAGATATG 1440
 90 QY 1441 CCTTAAACACATACTCTGCCGATCTAAATTACAGCCCTATTGGTATGCTTTGGGATT 1500
 |||||||
 Db 1441 CCTTAAACACATACTCTGCCGATCTAAATTACAGCCCTATTGGTATGCTTTGGGATT 1500

Art Unit: 1647

5 Qy 1501 CTCCTCATGCTTAGAAAGTTCCAAATGTTATAAAGTAAATGGCAGTTGAAGTCAAA 1560
 Db 1501 CTCCTCATGCTTAGAAAGTTCCAAATGTTATAAAGTAAATGGCAGTTGAAGTCAAA 1560

Qy 1561 TGTACATAGGCAAAGCAATCAAGCACCAGGAACGTGTTATGAGGAACACACCCAAAGA 1620
 Db 1561 TGTACATAGGCAAAGCAATCAAGCACCAGGAACGTGTTATGAGGAACACACCCAAAGA 1620

10 Qy 1621 TGAATTATTTTGAGACTGTCAGGAAGTAAATAAATAGGAGCTTAAGAAAGAACATT 1680
 Db 1621 TGAATTATTTTGAGACTGTCAGGAAGTAAATAAATAGGAGCTTAAGAAAGAACATT 1680

15 Qy 1681 GCCTGATTGAGAAGCACAACGTAAACCACTGAGCCGCTGGGGTGTAAATGGTAGCATTCTT 1740
 Db 1681 GCCTGATTGAGAAGCACAACGTAAACCACTGAGCCGCTGGGGTGTAAATGGTAGCATTCTT 1740

Qy 1741 CTTTGGCAATACATTGATTGTTGATGAAATATAATTAACAGCAATAGAGAAATGAATT 1800
 Db 1741 CTTTGGCAATACATTGATTGTTGATGAAATATAATTAACAGCAATAGAGAAATGAATT 1800

Qy 1801 ATAACTAGACATCTGCTGTTATCACCATAGTTGTTAATTGCTTCCTTTAAATAAA 1860
 Db 1801 ATAACTAGACATCTGCTGTTATCACCATAGTTGTTAATTGCTTCCTTTAAATAAA 1860

25 Qy 1861 CCCATTGGTAAAGTCAAAAAAAAAAAAAAA 1893
 Db 1861 CCCATTGGTAAAGTCAAAAAAAAAAAAAAA 1893.

30 De Robertis's SEQ ID NO: 10 encodes the amino acid sequence of SEQ ID NO: 9

and SEQ ID NO: 9 is the amino acid sequence of human frzb-1 (page 6, lines 29-31;

Figures 9 and 10). De Robertis's SEQ ID NO: 9 is identical to the present application's

SEQ ID NO: 9, as indicated below (Qy = the present application's SEQ ID NO: 9) (Db =

De Robertis's SEQ ID NO: 9):

35 AAW41254
 ID AAW41254 standard; protein; 325 AA.
 XX
 AC AAW41254;
 XX
 40 DT 09-JUL-1998 (first entry)
 XX
 DE Human "frazzled" frzb-1.
 XX
 45 KW Growth factor; frazzled; frzb-1; Wnts antagonist; human;
 KW tumour suppressor; cancer.
 XX
 OS Homo sapiens.
 XX
 50 PN WO9748275-A1.
 XX
 PD 24-DEC-1997.
 XX
 55 PF 19-JUN-1997; 97WO-US010942.
 XX
 PR 20-JUN-1996; 96US-0020150P.
 PR 18-JUN-1997; 97US-00878474.
 XX
 60 PA (REGC) UNIV CALIFORNIA.
 XX
 PI De Robertis EM, Bouwmeester T;
 XX
 DR WPI; 1998-062760/06.
 DR N-PSDB; AAV14017.
 XX
 65 PT New isolated growth factors - with neurotrophic, growth or
 PT differentiation factor activity, tumour growth suppressor activity or
 PT mesoderm differentiation activity.
 XX
 70 PS Claim 6; Fig 9; 48pp; English.
 XX
 CC The present sequence is the human growth factor protein "frazzled" frzb-
 CC 1. frzb-1 is an antagonist of Wnts in vivo, and thus is believed to find
 CC utility as a tumour suppressor gene, since overexpressed Wnt proteins
 CC cause cancer. Frzb-1 may also be a useful vehicle for solubilisation and

Art Unit: 1647

De Robertis also discloses a complex comprising a substantially pure frzb-1 protein complexed with at least one Wnt protein (claim 12, page 26). Accordingly, De Robertis discloses a complex comprising a substantially pure frzb-1 protein comprising the amino acid sequence of SEQ ID NO: 9 complexed with at least one Wnt protein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

40 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The present specification discloses that “substitutional, deletional, or insertion mutants of the novel polypeptides may be prepared by in vitro or recombinant methods and screened for immuno-crossreactivity with cerberus, frzb-1, or PAPC and for cerberus

antagonist or agonist activity" (page 5, lines 31-35). Hence, it is unclear how to construe the term "frzb-1 protein" because it is unclear if "substitutional, deletional, or insertional mutants" are encompassed by the term "frzb-1 protein." The metes and bounds are not clearly set forth.

5

Conclusion

No claims are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (571) 272-0887.

10 IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306
15 AFTER FINAL (703) 872-9307

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (571) 273-0890.

20 ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

David Romeo

25 DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

30 DSR
MAY 26, 2004